

Labelling & Naming

– European Biosimilars Group (EBG) perspective

>400 Million patient days worldwide clinical experience with EU biosimilar medicines

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Labelling and naming for biosimilar medicines

Agenda

Labelling – The European (EU) labelling approach, the way for building confidence

Naming – EU naming system and the use of unique product names

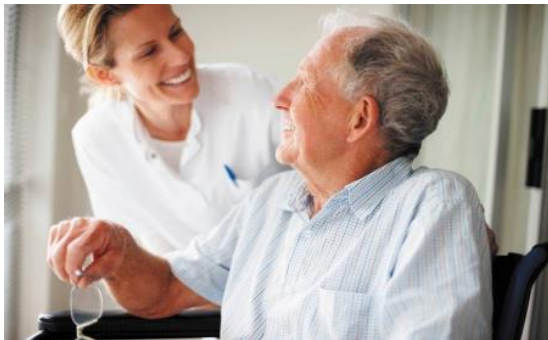
Labelling – Executive summary (1)

- ✓ *“A biosimilar is a biological medicinal product that contains a version of the active substance of an already authorised original biological medicinal product.”*
- ✓ *“A biosimilar is a biological medicinal product making reference to an already authorised original biological medicinal product. It is systematically engineered to match this reference product with regards to quality, safety and efficacy.”*
- ✓ *“A biosimilar needs to be developed based on an extensive head to head comparison with this reference product, to ensure close resemblance in physicochemical and biological characteristics, safety and efficacy.”*
- ✓ *“The posology and route of administration of the biosimilar must be the same as those of the reference medicinal product”.*

Labelling – Executive summary (2)

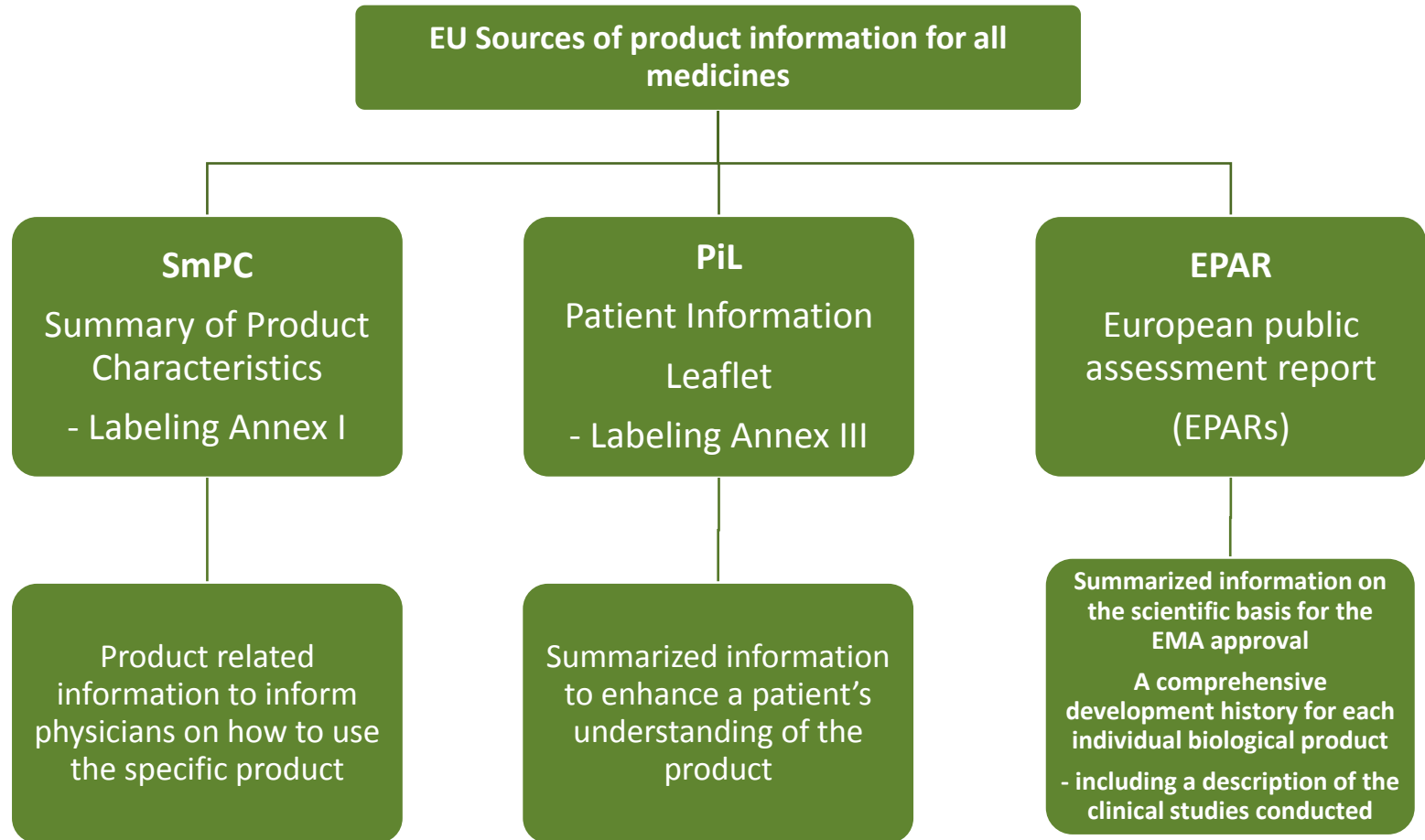
- ✓ A biosimilar product is **only approved**, once all these **stringent requirements** have been fulfilled and the biosimilar has been demonstrated to be of **comparable quality, safety and efficacy** to the **reference product**.
- ✓ Consequently, the European Medicines Agency approves their **medical use to be the same** as that of the reference product and requires the **label of the biosimilar product**, describing its medical use, to be **consistent** with that of the **reference product**

EGA – EBG Position Statement



- EGA supports clear and transparent product information for all medicinal products in the EU, including biosimilar medicines
- EGA considers the current system of product information for biosimilar medicines in the EU adequate, reliable, safe and transparent as it enables:
 - prescribers and patients to safely and effectively use biosimilar medicines (through SmPC and PiL)
 - the public to retrieve information on the biosimilar product's submitted data package, the scientific evaluation by the CHMP/EMA, the rationale for the approval as well as post-authorisation information on the biosimilar product (through the biosimilar's EPAR)

Europe ensures a clear structure & use of product information



Continuation of labels consistent between the reference product and biosimilar medicines is a must

- in line with scientific principles of biosimilarity and legal requirements
- fully transparent
- proven since 2006 to be the model supporting the safe and effective use of biosimilar medicines in Europe and in many countries around the globe

- is generating trust in the pioneering European authorisation system
- is ensuring that all the key information is available to the patients and the healthcare professionals
- Is avoiding confusion at the prescribers and patients level while building the trust on these needed medicines



The proven EU labelling model for biosimilar products should not be dismantled now for competition purposes !

Deviations create risks for good use of biosimilar medicines

Any deviations in a biosimilar's product information compared to the reference product's product information :

- ❖ could create **unnecessary confusion** and deepen **misinterpretation** of the **biosimilarity concept**
- ❖ **mislead** healthcare professionals and patients
- ❖ would create a situation where biosimilar medicines are **no longer considered as therapeutic alternatives** to their reference products
- ❖ lead to **potential medication errors** and withhold biosimilar medicines from patients in need
- ❖ do not reflect **totality of evidence supporting approval** of biosimilar medicines - being comparable to reference product with regards to quality, safety and efficacy
- ❖ undermine specific legal basis for biosimilar medicines approval

Naming in Europe – Executive summary

- ✓ The EU naming system - which clearly differentiates between product name and INN - is highly reliable and the model for the world.
 - ✓ There is ample evidence the EU naming system facilitates reliable identification and therefore guarantees a robust product safety reporting system
- ✓ Traceability works extremely well with existing, well tested identifiers, like brand name, in European countries.
- ✓ The biosimilarity concept has proven to guarantee comparable quality, safety and efficacy and therefore support same INN naming for the biosimilar medicines and the reference product

EU naming system clearly differentiates between product name and INN



EU directive 2001/83/EC:

Name of the medicinal product:

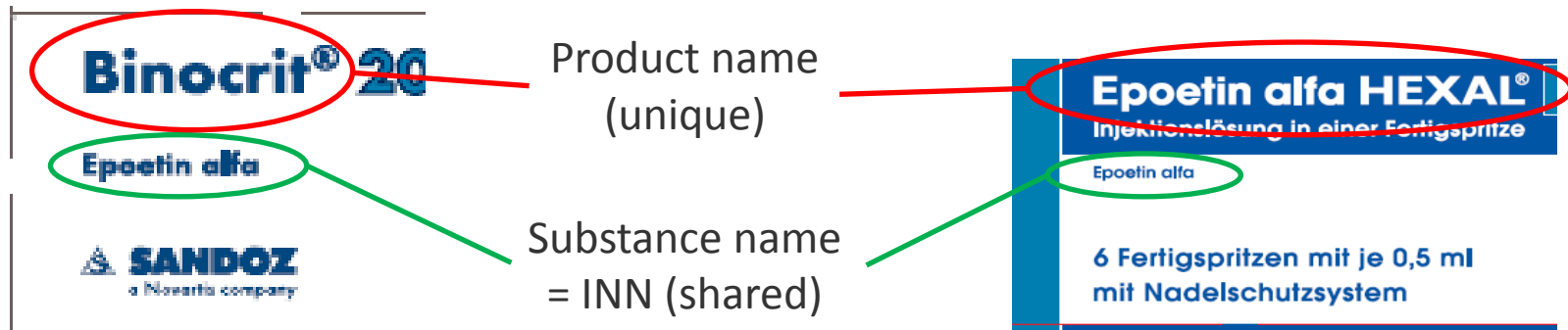
1. The name, which may be either an **invented name** not liable to confusion with the common name, or
2. a **common** or scientific **name accompanied by** a trade mark or the name of the **marketing authorisation holder**.

The international non-proprietary name (INN):

is the common name for the active substance recommended by the World Health Organization.

The INN is stated in addition to and separately from the product name in all labeling.

Unique product names separate from the active substance names (INNs) are the best solution



- ▲ Clear identify any biological product
- ▲ Robust track & trace and pharmacovigilance - AE reporting
- ▲ Unambiguous prescription

Reporting by brand name is an efficient traceability tool in Europe – a Sandoz example

Epoetin alfa

127 mio patient days

▲ **97,55% of cases are reported with a brand names**

PSUR 22 Oct 2014

Filgrastim

7 mio patient days

▲ **99,65 % of cases are reported with a brand name**

PSUR 29 Aug 2014

Somatropin

69 mio patient days

▲ **98,36 % of cases are reported with a brand name**

PSUR 12 Nov 2014

Reporting by brand name is an efficient traceability tool in Europe – similar examples

- ▲ Hospira reports 99% identification of its biosimilar Epo by trade name¹
- ▲ European regulators report 96.2% product identification across three product classes (filgrastim, epoetin, somatropin)²
- ▲ Recent European Commission survey³ showed that
 - the majority of Member States strongly supports that biosimilars should be closely aligned with their reference product
 - it is not problematic to identify the biological products which are subject to adverse reaction reports
- ▲ Italian Database - Reporting Adverse reactions of Biologicals and traceability: traceability by identifiable brand⁴
 - name was indicated in 94.8 % of biologicals
 - higher level of completeness: 98,7% for biosimilars

¹ http://www.hospira.com/Images/What's%20In%20a%20Name%20-%20Hospira%20Policy%20Paper%20-%20Oct%202013_32-92092_1.pdf

² http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2012/05/WC500127934.pdf

³ PHARM 639-Pharmaceutical Committee 23.10.2013 -71st meeting.

⁴ <http://www.ncbi.nlm.nih.gov/pubmed/25255847>

EGA acknowledges some other regions want differentiation beyond product name

WHERE

- ▲ Some countries do not require product name separate from INN
(e.g. US)
- ▲ Some countries want INN prescription for medicines in general, but not for biologics
- ▲ Some countries want second level of differentiation in addition to brand name

HOW

- ▲ INN itself to stay the same
- ▲ Specific product identified by additional component, separate from INN
- ▲ For ALL biologics, not only biosimilars
- ▲ To include no component that identifies regulatory pathway
 - ▲ To apply retroactively
 - ▲ Voluntary for regulatory agencies
- ▲ Harmonized globally by WHO INN office



EGA/EBG position on proposed BQ identifier – only for use outside Europe

- ▲ EGA welcomes WHO's efforts to counteract proliferation of divergent naming systems for biologics
- ▲ EGA supports independence of BQ from INN, voluntariness, applicability to all biologics, retroactivity, administration by WHO
- ▲ BQ should be used only where it adds value
- ▲ BQ must be linked to company, not manufacturing site as proposed
- ▲ BQ must be easy to remember – company name is easiest than a random code
- ▲ Different BQ options should be generated and thoroughly user tested to facilitate the final decision

In Conclusion - EGA/EBG is convinced no additional identifier is needed in Europe



Generics Bulletin, October 2014

BIOLOGICAL DRUGS

Biological qualifier is not needed in the EU

Proposals by the World Health Organization (WHO) to introduce a qualifier for biological drugs do not need to be implemented in the European Union (EU), according to a statement by the European Medicines Agency (EMA).

“The EMA’s comments on the biological qualifier scheme will be communicated to the WHO,” the agency stated, “particularly that there is no need to implement the biological qualifier scheme in the EU.” This, the regulator said, was because “biologicals have a well-established identification system in Europe.”

According to the WHO’s proposals (*Generics bulletin*, 8 August 2014, page 25), the scheme would involve a voluntary qualifier – which would be used in addition to international non-proprietary names (INNs) – consisting of a four-letter code assigned at random to biological active ingredients. The WHO intends the scheme

EMA interview with Generics Bulletin:

« there is no need to implement the biological qualifier scheme in the EU »

« biologicals have a well-established identification system in Europe »

Labelling and naming – take away messages

- ▲ EU labelling approach for biosimilar medicines since 2006 is the right method
- ▲ On naming - using product name is the way forward while maintaining the existing INN system
- ▲ Outside Europe - BQ proposal requires further refinement and should only be considered where needed.

- ▲ AE Adverse Event
- ▲ BQ Biological Qualifier
- ▲ EBG European Biosimilars Group
- ▲ EGA European Generic medicines Association
- ▲ EU European Union
- ▲ INN International Nonproprietary Name
- ▲ PV Pharmacovigilance
- ▲ WHO World Health Organisation

**Thank you all for your
attention.**

Danke !

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